510(k) Summary K011901

FEB 01 2002

N-1. ADMINSTRATIVE INFORMATION

N-1.1 Name and address

Submitted by: Survivalink Corporation
5430 Feltl Road
Minneapolis, MN 55343

Contact Person: Sew-Wah Tay, Ph.D.
Telephone No.: 952-939-2942
Facsimile No.: 952-939-4191

Date Prepared: June 15, 2001

N-1.2 Device Name

Common or Usual Name: Automated External Defibrillator (AED)
Device Name: FirstSave™ Automated External Defibrillator

N-1.3 Classification

Class III MKJ (AED)

Classification Name: a) DC defibrillator
21CFR§870.5300; Class II
b) Cardiac Monitor (Cardiotachometer and Rate Alarm)
21CFR§870.2300; Class II

N-1.4 Applicant

Applicant's Name: Survivalink, Corporation
5430 Feltl Road
Minneapolis, MN 55343

N-2. PREDICATE DEVICES

FirstSave STAR Biphasic AED, models 9200 and 9210 (K010214), Powerheart AED (K993533)

N-3. INDICATION FOR USE

The FirstSave STAR Biphasic AED is intended to be used by personnel who have been trained in its operation. The user should be qualified by training in basic life support or other physician-authorized emergency medical response. The device is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Post-resuscitation, if the victim is breathing, the AED should be left attached to allow for acquisition and detection of the ECG rhythm[1]. If a shockable ventricular tachyarrythmia recurs, the device will charge automatically and

advise the operator to deliver therapy. The device is intended for use on persons older than eight years of age[2].

(1) American Heart Association "Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care" Circulation Supplement Vol 102(8) Aug. 2000, page I-66.
(2) American Heart Association "Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care" Circulation Supplement Vol 102(8) Aug. 2000, page I-64.

N-4 DEVICE DESCRIPTION

The FirstSave STAR Biphasic AED is a biphasic portable battery operated semi-automatic low power DC defibrillator. The device's diagnostic algorithm analyzes the patient's cardiac rhythm to determine shockable versus non-shockable EKG rhythm. The operator then pushes the button to deliver the defibrillation shock. The FirstSave STAR Biphasic feature includes:

- Lithium battery
- Single user button for Rescue or Resume
- LED diagnostic panel
- Non-volatile status indicator
- Voice prompts
- Biphasic truncated exponential defibrillation waveform
- RhythmX ECG analysis algorithm

N-5. SUBSTANTIAL EQUIVALENCE

The Company's modified FirstSave STAR Biphasic covered by this submission is substantially equivalent to other legally marketed semi-automatic low power DC defibrillators. Specifically, the FirstSave STAR Biphasic is substantially equivalent to the Survivalink FirstSave STAR Biphasic previously cleared under the 510(k) K010214. and the PowerHeart (K993533) The FirstSave STAR Biphasic has the same general indication for use, similar principles of operation, and similar technological characteristics as the previously cleared predicate devices. The differences this device and its predicate devices do not raise new questions of safety or efficacy.

N-6. PERFORMANCE DATA

The performance test data is provided in the 510(k) submission. The performance data demonstrate that the device complies with the applicable sections of AAMI DF39-1993, IEC 601-2-4.

Tests results include rhythm detection, EMC, charge time, pulse shape, battery capacity, defibrillation recovery, design verification and validation data for hardware and software incorporated into the FirstSave STAR Biphasic. Environmental tests performed on the finished device include foreign object and water penetration, drop, vibration, humidity, altitude and temperature.

Test data demonstrate that the safety and effectiveness of the Modified FirstSave STAR Biphasic in this submission is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 01 2002

Mr. John Carline
Manager of Regulatory Affairs
Survivalink Corporation
5420 Feltl Road
Minneapolis, MN 55343

Re: K011901
Trade Name: FirstSave STAR Biphasic AED
Regulation Number: 21 CFR 870.1025
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: October 16, 2001
Received: October 17, 2001

Dear Mr. Carline:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

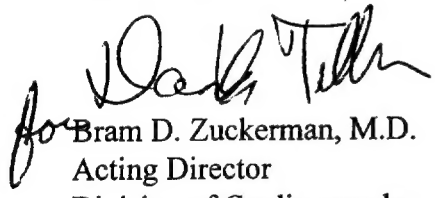
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K011901

Device Name: FirstSave STAR Biphasic AED

Indication for Use

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011901